

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE>

{BLISTER CARD}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PetStar Soft Flea Collar, 180 mg/g, medicated collar

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains Permethrin (Cis:Trans 40:60)

What's in this collar?

Each collar contains 456mg (180 mg/g) Permethrin (Cis:Trans 40:60) which is a Pyrethroid.

3. PHARMACEUTICAL FORM

Medicated collar

4. PACKAGE SIZE

1 collar

5. TARGET SPECIES

Cats

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

What does this collar do?

PetStar Soft Flea Collar contain an insecticide that kills fleas on your cat and prevents their return for up to 4 months. However, as fleas can also live in your carpets and in your cat's bed, you should treat these areas with a suitable insecticide and vacuum regularly.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use:

Do not remove the collar from the blister until ready for use. Fasten around your cat's neck (coloured side facing outwards), leaving enough room to insert 2 fingers between the collar and neck – remember to loosen the collar if fitted on to a growing cat. Cut off any collar sticking out beyond the buckle. Wrap this cut-off in a bag and

throw it in your dustbin. Keep the empty blister card for reference until the collar is thrown away.

For external use only.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

Is this collar safe for my cat?

Yes. However, you should not use it if your cat is less than 12 weeks old. Do not allow the collar to come into contact with pregnant or nursing females. In all of these cases, use a flea comb or speak to your vet.

Precautions:

What precautions should I take to protect my cat?

For external use only. Do not use any other flea control products on your cat whilst using this collar or within 7 days of removing it. Leave room between the collar and your cat's neck to allow for growth and to prevent irritation – if skin irritation does occur, remove the collar straight away. Never allow any animal to chew the collar. If signs of disease persist or appear consult your Veterinary Surgeon.

What precautions should I take to protect myself and my family?

Wash hands thoroughly with soap and water after handling the collar. Do not smoke, eat or drink while handling the collar. Do not allow children to play with the collar or to chew and suck on it.

A pet wearing a flea collar should not sleep in bed with people, particularly children.

10. EXPIRY DATE

EXP: end {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

Do not remove the collar from the blister until ready for use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the collar or used packaging. Dispose of empty packaging, excess collar length, used and unused collars in the household refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only

AVM-GSL

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by
PetStar UK
PO Box 104
Haverhill
Suffolk
CB9 8WZ

16. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

16516/4036

17. MANUFACTURER’S BATCH NUMBER

ManA 16576

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {NATURE/TYPE}

Not applicable

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

Not applicable

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

Not applicable

1. NAME OF THE DILUENT

The 'trade' name with a brief description or a more describing way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3. ROUTES OF ADMINISTRATION

[According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]

Read the package leaflet before use.

4. STORAGE CONDITIONS

<Do not store above <25 °C> <30 °C>.>
<Store below <25 °C> <30 °C>.>
<Store in a refrigerator.>
<Store and transport refrigerated.>*
<Store in a freezer.>
<Store and transport frozen.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***
<Store in the original <container><package>.>
<Keep the {container}**** tightly closed.>
<Keep the {container}**** in the outer carton.>
<in order to protect from <light> <and> <moisture>>
<Protect from light.>
<Store in a dry place.>
<Protect from direct sunlight.>
<This veterinary medicinal product does not require any special storage conditions.>
<This veterinary medicinal product does not require any special temperature storage conditions.>

5. BATCH NUMBER

<Batch> <Lot> <BN> {number}

6. EXPIRY DATE

<EXP {month/year}>

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

Not applicable

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

4. INDICATION(S)

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

[Immunologicals ONLY - For injectables containing mineral oil, the following statement should be included:]

<To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[It is recommended that the following reference to the VMD Website is included:]

<Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

<15. OTHER INFORMATION>

[Distribution category]

Vm <number>

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

Not applicable

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is breached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S)<User Warnings>

15. EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]

<Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.>

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-V

POM-
VPS

NFA-VPS

AVM-
GSL

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

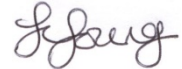
20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 09/08/2017

A handwritten signature in black ink, appearing to read 'J. Berg', is written below the approval date.